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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,433	01/23/2006	Ming Li	14184.0005USWO	1876
23552 7590 08/02/2007 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER MCCORMICK, MELENIE LEE	
			ART UNIT	PAPER NUMBER
			1655	
			MAIL DATE	DELIVERY MODE
			08/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/538,433	LI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Melenie McCormick	1655	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 29 May 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-15 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendments with remarks submitted 29 May 2007 have been received and considered.

Claims 1-12 and 16-20 have been cancelled. New claim 21 has been added.

Newly submitted claim 21 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The new claim is directed to a method of enhancing angiogenesis and myogenesis in an animal. The previously examined claims were drawn to a method for treating skeletal muscle injuries and a method of preparing an organic extract from *Geum Japonicum* Thunb. These previously examined methods are distinct from the newly claimed method of claim 21 because the methods as claimed are not capable of use together. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 21 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 13-15 are presented for examination on the merits.

Art Unit: 1655

***Claim Rejections - 35 USC § 101***

Applicants have cancelled claim 12, therefore the previous rejection under 35 U.S.C. 101 has been withdrawn.

***Claim Rejections - 35 USC § 112***

Applicants have cancelled claims 8,10, 12 and 20, therefore the previous rejection under 35 U.S.C. 112, second paragraph has been withdrawn.

***Claim Rejections - 35 USC § 102***

Applicants have cancelled claims 1-4, 6-7, 9-11 and 19, therefore the previous rejection under 35 U.S.C. 102(b) has been withdrawn.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Reiji et al. (JP 03190809) for reasons set forth in the previous office action which are discussed below.

A method for treating skeletal muscle injuries, soft tissue trauma, operation, cut, burn, ulcers, bone defects, or bone fractures in an animal, comprising administration to the animal suffering from such conditions an effective amount of the extract of Geum Japonicum Thunb obtained by extracting Geum Japonicum Thunb in methanol is claimed. Dependent claims are drawn to the method wherein the animal is a mammal, in particular, a human.

Reiji et al. beneficially teach a skin medicine which comprises an extract of Geum Japonicum. Reiji et al. further teach that the extract is prepared using ethanol (C1-C4 alcohol). It is further disclosed by Reiji et al. that the extract is useful for improving chapped skin (a skin injury) (see e.g. English Abstract). The adjustment of particular conventional working conditions (e.g. providing the extract treatment to a particular animal) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to supply an alcoholic extract (including an ethanolic extract) to an individual suffering from chapped skin, which would be a form of soft tissue trauma, as claimed. This is especially true in light of Applicant's disclosure that an organic extract of Geum Japonicum Thunb is useful for treating damaged soft tissue, including skin (see e.g. Specification- page 1, lines 6-7). One of ordinary skill in the art at the time the claimed invention was made would have been motivated and would have had a reasonable expectation of success in doing so based upon the beneficial teaching

Art Unit: 1655

of Reiji et al. that such an extract is useful for improving chapped skin, which is a type of skin damage/trauma.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicants argue that Reiji et al. do not teach the instantly claimed method for treating skeletal injuries, soft tissue trauma, operation cut, burn, ulcers, bone defects, or bone fractures. This is not persuasive, however, as Reiji et al. teaches that the composition is useful in treating a type of skin damage or trauma, namely, chapped skin. Applicants disclosure does not exclude chapped skin from among the possible skin traumas.

Applicants further argue that Reiji et al. do not teach an organic extract from Geum Japonicum Thunb comprising tannins comprising gamins A,B,C,D,E, and F and triterpenes comprising 2-hydroxyoleanolic acid, 2-hydroxyursolic acid, 2,19-dihydroxy-ursolic acid, 2-alpha, 19-alpha-dihydroxy-3-oxo-12-ursen-28-oic acid, ursolic acid, epimolic acid, maslinic acid, euscaphic acid, tormentic acid, and 28-beta-D-glucoside of tormentic acid. Applicants argue that Reiji et al. do not teach an extract obtained by a method of extracting a plant of Geum Japonicum Thunb with an alcohol selected from

Art Unit: 1655

the group consisting of C<sub>1</sub>-C<sub>4</sub> alcohols, drying the extract into a dried powder, successively extracting the powder with C<sub>6</sub> alkane, EtOAc and an alcohol selected from the group consisting of C<sub>1</sub>-C<sub>4</sub> alcohols, and drying the extract into a dried powder, therefore Reiji et al. do not teach Applicants claimed invention. This is not persuasive, however, as Reiji et al. do teach that the composition used in the method is obtained by extraction with ethanol. Therefore, although Applicant's may have performed further extraction steps beyond a first extraction with a C<sub>1</sub>-C<sub>4</sub> alcohol, in order to obtain an extract with the instantly claimed constituents of the Geum Japonicum Thunb, these constituents would necessarily be present following the first extraction step with a C<sub>1</sub>-C<sub>4</sub> alcohol, which is what is taught by Reiji et al. Therefore, the composition used in the method taught by Reiji would necessarily contain the instantly claimed constituents.

The rejection is therefore deemed proper and is maintained.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1655

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Art Unit: 1655

Melenie McCormick  
Examiner  
Art Unit 1655

A handwritten signature in black ink, appearing to read "CHRISTOPHER R. TATE", written over a horizontal line.

CHRISTOPHER R. TATE  
PRIMARY EXAMINER